Executive Summary

The TSCA New Chemicals Program has a short time period (up to 90 days as mandated by law) to review the safety of a new chemical substance and make a determination on whether to allow the new chemical substance to enter commerce, often with very limited experimental test data on the human health and ecological effects of the new chemical substance. To address these challenges, the program uses screening-level methods and conservative assumptions that allow EPA to quickly determine whether the potential human health and environmental risks posed by the new chemical substance are of concern or may be of concern. The screening-level approach is applied to all components of the risk assessment: chemistry, human health and environmental hazard, environmental fate, environmental release, and exposure to the general population, consumers, occupational workers, and environmental organisms. These approaches are designed to provide a conservative estimate of risk, and in some instances due to a lack of information or other factors, can over-estimate risk. When EPA finds that there are no risks of concern using these methods, EPA has high confidence in that conclusion. In those cases where EPA fins, using these approaches, that a new chemical substance may have or does have risks of concern, these risk estimates that are likely to be higher than what actually occurs in the real world..

In 2022, EPA performed a TSCA new chemical risk assessment on 18 separate premanufacture notices (PMNs) for chemical substances intended to be used as alternative fuel sources. The purpose of this document is to provide additional information to further describe the risk assessment approach and risk estimates presented in EPA's 2022 integrated risk assessment[1]. The integrated risk assessment describes how each of the 18 PMN substances is made by blending a small amount of plastic-derived feedstock (raw materials used to produce another product in an industrial process) with a large amount of petroleum-based feedstock in a refinery. Even though these new fuels have similar chemical composition as existing petroleum fuels, they are nonetheless "new chemicals" under TSCA and still must go through the new chemicals review process. This risk summary and characterization document provides some background, and explains the assessment approach and results. As part of this, key assumptions, strengths, uncertainties, and limitations are highlighted. For the risk assessment, EPA evaluated risks to workers, consumers and the general population, including risk to people who live close to facilities with chemical releases (i.e., "fenceline" communities).

Each of these 18 PMN substances is a complex mixture comprised of different ratios of paraffinic, isoparaffinic, naphthenic, olefinic, and aromatic (PIONA) molecules. The new chemical submissions provided the EPA with measured PIONA profile information for each new chemical substance. The measured PIONA profiles do not show significant variation from that of a traditional petroleum fuel stream. Additionally, these 18 new chemical substances are

[1] U.S. EPA. 2022. *Integrated Risk Assessment for Chevron Waste Plastic Fuels (P-21-0144, 145, 146, 147, 148, 149, 150, 152, 153, 154, 155, 156, 157, 158, 160, 161, 162, and 163)*

expected to follow the typical lifecycle of petroleum-based fuels. EPA uses a suite of models[2] and conservative assumptions to estimate environmental release and exposure to ensure the assessment is protective of human health and the environment.

EPA also uses the PIONA profile in its human health and environmental hazard assessment. EPA has a tiered approach for identifying the appropriate hazard value(s) for use in risk assessment. This tiered approach begins with having toxicity data on the actual PMN substance as the preferred choice. This information was not available for these 18 PMN substances. The next tier involves EPA identifying appropriate petroleum analogs that have a similar PIONA profile and for which toxicity information exists. In this case, EPA identified "Stoddard solvent" as an appropriate petroleum analog for some of the 18 PMN substances. The decision to use "Stoddard solvent" as the analog was a conservative, health protective assumption that was made because EPA lacked information on the PMN substances. Again, due to a lack of accurate information on the specific composition of the PMN substances, EPA assumed that the PMN mixture is 100% Stoddard solvent. As a last tier, EPA used hazard information on individual constituents in the PIONA profiles for the remaining PMNs.

For exposure assessment, EPA develops conservative exposure scenarios which are designed to provide conservative estimates of exposure; this allows EPA to have high confidence – when it finds no risks of concern – that this is in fact the case. In some instances, due to a lack of information on which to based exposure estimates, the conservative assumptions can lead to an over-estimate of risk. For one of the PMN substances in this integrated risk assessment (a jet fuel), the Agency divided the total projected future annual production volume of the new jet fuel by the total number of locations expected to receive the fuel, and then assumed each location could be an end-use location (e.g., airport) and that all the fuel would be burned there. The scenario that was modeled effectively presumed that every plane at the airport was idling on a runway burning an entire tank's fuel without ever taking off, that the components of the fuel that contribute to c risk are not fully combusted and are present in the exhaust, and that residents living nearby (in a fenceline community) would continuously breathe the exhaust each day over many years in their lifetime.

When coupled together, the conservative assumptions for both the hazard and exposure assessments for the 2022 integrated risk assessment for the 18 PMN substances led to an overestimate of risk. For example, as described in Section 5.4 of the 2022 integrated risk assessment, the assessment resulted in an estimated extra cancer risk of 1 in 4 for people exposed 100 meters (i.e., at the "fenceline") from the end-use (combustion) of one of the PMN substances (a jet fuel). However, this exposure scenario, as described above, is not one that would realistically ever be expected to occur.

Given the short time-frame for new chemical reviews and the similarities in the PIONA profiles to traditional fuels, instead of using additional resources to develop a refined and more accurate estimate of the human health risks posed by these 18 PMN substances, EPA

[2] https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca

determined that the similarities in the PIONA profiles supported the assumption that worker and fenceline community risk from these PMN substances are similar to those of existing petroleum fuels and applied appropriate risk mitigation measures to protect both human health and the environment. Specifically, EPA's consent order required the company to comply with existing regulations under the Clean Air Act, OSHA, DOT, and Coast Guards as well as anything else that was applicable to the manufacture, transportation, storage, dispensing, use and disposal of these new fuels (see Docket # EPA-HQ-OPPT-2023-0245 in regulations.gov for copies of the final consent order for these 18 PMNs).

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1 Introduction

The global energy sector has been shifting away from petroleum fuel sources over the past few decades. Domestically, one example of such a shift is the use of corn-based ethanol in transportation fuel, as most vehicles today run on gasoline containing 10% ethanol. Other innovations and process changes have also been developed to replace a portion of petroleum-based fuels with fuels derived from alternative sources.

One example innovation is the blending of petroleum-based feedstock[3] with bio- or waste-derived feedstock at the refinery to make a new fuel. Ethanol is a single chemical substance already on the TSCA chemical inventory. In contrast, these new fuels are often complex hydrocarbon mixtures designed to mimic the mixture normally found in the petroleum stream and are typically not listed on the TSCA chemical inventory. Therefore, they are considered new chemicals under TSCA and are subject to the new chemicals review process.

Under TSCA, EPA's review process for all new chemical substances examines the lifecycle of a chemical, including manufacturing, processing, distribution, use, and disposal. EPA applies a conservative, screening level risk assessment approach to determine if the new chemical substance poses risk to humans and the environment. As part of this approach, EPA typically makes multiple conservative assumptions for hazard and exposure to ensure protection of human health and the environment.

In January 2022, EPA announced an effort to standardize the review of certain new chemicals intended to be used as transportation fuels due to the growing number of premanufacture notices (PMNs)[4] submitted to EPA from companies who want to make transportation fuels by blending bio- or waste-derived feedstock with petroleum-based feedstock. In 2022, EPA developed a single risk assessment[5] that provides the evaluation of 18 PMNs using the standardized approach to evaluate risks to workers, consumers and the general population (including risk from "fenceline" exposures), as well as risks to environmental organisms. That risk assessment has been the subject of significant inquiry from the public and stakeholders. The purpose of this document is to provide additional information to describe the risk assessment approach and risk estimates presented in the 2022 integrated risk assessment[6] and summarizes the key assumptions, strengths, uncertainties, and limitations. This document provides summary and characterization information; technical details of EPA's assessment methodology and assumptions are found in the complete integrated risk assessment[7]. This document is organized as follows:

[3] Feedstock - raw materials used to produce another product in an industrial process
[4] Since the announcement, EPA has received approximately 40 such notices.
[5] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-biofuel
[6] U.S. EPA. 2022. *Integrated Risk Assessment for Chevron Waste Plastic Fuels (P-21-0144, 145, 146, 147, 148, 149, 150, 152, 153, 154, 155, 156, 157, 158, 160, 161, 162, and 163)*
[7] *Ibid*

- Section 2 describes the PIONA composition/conclusion.
- Section 3 presents an overview of EPA's hazard assessment approach.
- Section 4 presents an overview of EPA's exposure assessment approach.
- Section 5 characterizes the risk estimates, as well as key strengths and uncertainties.
- Section 6 provides a summary of the conclusions.

2 PIONA Composition: EPA's Conclusion

As detailed in Section 2 of the 2022 integrated risk assessment, each of these 18 PMN substances is a complex mixture comprised of different ratios of paraffinic, isoparaffinic, naphthenic, olefinic, and aromatic (PIONA) molecules[8]. The new chemical submissions provided the EPA with measured PIONA profile information for each new chemical substance. The measured PIONA profiles do not show significant variation from that of a traditional petroleum fuel stream[9].

EPA uses the PIONA profile in its human health and environmental hazard assessment. EPA has a tiered approach for identifying the appropriate hazard value(s) for use in risk assessment. This tiered approach, detailed in Appendix A of the integrated risk assessment, begins with having toxicity data with the PMN substances as the preferred choice. This information was not available for these 18 PMN substances. The next tier involves use of petroleum analog with a similar PIONA profile, which was done for some of the 18 PMN substances. As a last conservative tier, hazard information on individual constituents for the appropriate PIONA profile was used for the remaining PMN substances where higher tier data were not available.

3 Hazard Assessment Summary

EPA's hazard assessment for these chemical mixtures follows the Agency guidance (US EPA 1986 and 2000)[10] which includes a hierarchy of data preferences. In the hierarchy,

[8] Fuel streams such as these are comprised of dozens of different paraffinic (isoparaffinic), naphthenic, olefinic, and aromatic (P[I]ONA) molecules, which makes determining their chemical makeup challenging. PIONA profiles are commonly used in the petroleum industry to characterize petroleum streams. The composition of these substances is variable since the fuels are defined using physical properties such as boiling point rather than their precise chemical makeup.

[9] The submitter claims that the PMN substances are chemically equivalent to their petroleum analogues. In order to establish this equivalency, they used a pilot plant to measure the P(I)ONA profiles for three conditions: a final stream with [redacted] alternative fuel streams. Results showed that, in general, there is no significant variation in the P(I)ONA profile for each range despite increasing amounts of alternative fuel streams. Given that there is very little variation overall, it is reasonable to conclude that the concentration of alternative fuel stream ([redacted] does not significantly change the hydrocarbon composition of the final fuel stream.

[10] U.S. Environmental Protection Agency 1986. "Guidelines for the Health Risk Assessment of Chemical Mixtures". Risk Assessment Forum, U.S. Environmental Protection Agency, Washington DC. EPA/630/R-98/002.

U.S. Environmental Protection Agency. 2000. "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures". Risk Assessment Forum, U.S. Environmental Protection Agency, Washington DC. EPA/630/R-00/002.

experimentally-derived test data on the mixture of interest, in this case each of the 18 PMN substances, are preferred (Tier 1) over data on sufficiently similar (i.e., analogous) mixtures (Tier 2), followed by data on individual constituents (Tier 3), if the first two options are not available. As part of this analysis, EPA considers which exposure routes (i.e., dermal, inhalation, oral), hazards (e.g., cancer and/or non-cancer) and pathways (e.g., water, environmental receptors) are appropriate for a particularly PMN.

There are no data on the specific mixture of interest for the 18 PMN substances (Tier 1) in this assessment and so PIONA profile information was used to determine the appropriate analogue (Tier 2) or constituent (Tier 3) to be used as noted in Section 2 above.

When data from analogous mixtures are not available, EPA considers whether there are available data on representative constituents. In some instances, data from Tier 2 was compared with data from Tier 3 and the more conservative value was chosen to ensure that the resulting assessment protects human health and the environment and is based on the most reliable data available.

Details can be found in the full risk assessment as follows:

- General methodology (Appendix A);
- Environmental Hazard (Sections 4 and Appendices D and E;
- Human Health (Section 5 and Appendices F and G); and
- Uncertainties (throughout, with summary in Section 8).

3.1 Human Health Hazard, Non-Cancer

No human health hazard data were submitted for any of the 18 PMNs. Hazards for each new chemical substance were identified based on information for the Tier 2 analogous mixtures and Tier 3 representative constituents. The submitter provided PIONA profile information for each of the new chemical substance mixtures. Based on this information, the analog mixture toxicity data were used for some of the 18 PMNs.

Constituents were identified based on either documented presence in the PMN substance or as a representative of the PIONA class for that specific PMN mixture. Using a database of petroleum constituent points of departure (PODs) (see Appendix F in the risk assessment), constituents of each PIONA class that are in the carbon range of the new chemical substance were identified

For each exposure route, non-cancer risks of the new chemical substance were estimated using one of two approaches: 1) using the POD for the appropriate analogous mixture if available; or

using the worst-case constituent[11] POD. If no suitable analogous mixtures were identified for a specific exposure route, then the risks were based on the worst-case constituent.

For non-cancer endpoints, Tier 2 analogous mixtures were identified as follows:

- Data available as a basis for an oral POD = 8/18 PMNs
- Data available as a basis for an inhalation POD = 12/18 PMNs
- Data available as a basis for a dermal POD = 12/18 PMNs

For non-cancer endpoints, Tier 3 worst-case constituents were identified as follows:

- Data available as a basis for an oral POD = 17/18 PMNs
- Data available as a basis for an inhalation POD = 17/18 PMNs

Thus, for non-cancer endpoints, if appropriate PODs were available with Tier 2 data (i.e., analogous mixtures) or Tier 3 data (i.e., constituents), the more conservative of the two (i.e, worst-case) was used to estimate non-cancer risk. If only Tier 2 or Tier 3 data were available, that POD was used. Occasionally, there was no POD information available for a particular PMN case or exposure pathway/receptor and so non-cancer risk was not estimated.

3.1 Human Health Hazard, Cancer

For cancer endpoints, the same approach used to identify analogous mixtures/constituents for non-cancer endpoints was used (i.e., based on PIONA profile). However, there were much less cancer data available and so there were only four hazard values from oral exposure studies (called oral cancer slope factors) identified. These cancer slope factors are for benzene, benzo[a]pyrene, 1,1-biphenyl and 1-methylnaphthalene.

For the inhalation exposure pathways, there were four hazard values available [called inhalation unit risk (IURs)]; two on individual constituents (benzene and benzo[a]pyrene) and two for analogous mixtures (commercial hexane and Stoddard solvent). For benzo(a)pyrene (Tier 3, constituent) a relative potency factor adjustment was made to estimate potency of polyaromatic hydrocarbons (PAHs) with four rings instead of five.

If there were no appropriate cancer data, an estimate of cancer risk was not calculated.

3.2 Environmental Hazard

EPA estimated acute and chronic ecotoxicity endpoints for fish, aquatic invertebrates, and algae with the 18 new chemical substances using available information for analogous mixtures (Tier

[11]The worst case constituent was the constituent with the lowest value obtained by dividing each POD (or its NOAEL-equivalent if the POD is a LOAEL) by the fraction represented by that PIONA class.

2) and information on individual constituents (Tier 3). These environmental endpoints are described in Section 4 of the Integrated Risk Assessment. The lowest acute and chronic toxicity endpoints for each new chemical substance were used to determine the environmental hazard and calculate the acute and chronic concentrations of concern (COCs). As per established EPA/OPPT methods, the application of assessment factors of 4 (algae) or 5 (fish and aquatic invertebrates) to the acute toxicity values results in acute COCs between 0.002 ppm (2 ppb) and 3.352 ppm (3352 ppb). As per established EPA/OPPT methods, application of an assessment factor of 10 to chronic toxicity values (*i.e.,* ChV) results in chronic COCs between 0.00003 ppm (0.03 ppb) and 0.177 ppm (177 ppb). The acute and chronic aquatic toxicity endpoints indicate that the 18 PMN substances are expected to range from moderate to high environmental hazard. Further details are described in Section 4 of the Integrated Risk Assessment.

4 Exposure Assessment Summary

EPA evaluated environmental and human exposure to each chemical from its entire lifecycle (see Figure 1). After these chemicals are manufactured at the refinery, they are typically shipped to bulk terminals for further blending, storage, and distribution. The actual fuel distribution chain is complex and EPA does not have specific information on every lifecycle step downstream from the refinery. The lifecycle step also varies for each chemical and for each type of fuel.

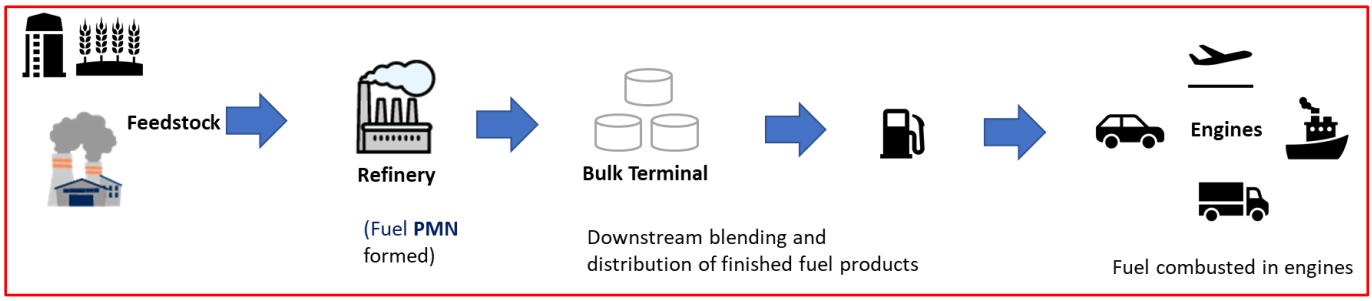

Figure 1 – Schematic of Alternative Fuel Source Lifecycle

For the exposure assessment, EPA assumed each chemical is manufactured, processed, and used at the maximum future projected production volume. EPA's assessment relied on a combination of submitter data (including worker exposure monitoring data), EPA models, and conservative assumptions. EPA uses the following models in to estimate environmental releases and exposures[12]:

- ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases). Used to estimate releases to the environment from manufacture/distribution. Also used to estimate occupational exposures.

[12] Ibid, footnote 2.

- IIOAC (Integrated Indoor-Outdoor Air Calculator). Used to estimate releases to air for exposure to the general population.
- E-FAST (Exposure and Fate Assessment Screening Tool). Used to estimate exposures to the general population and environmental organisms.
- CEM (Consumer Exposure Module). Used to estimate consumer exposures.

The assumptions and uncertainties vary by exposure scenario (both lifecycle stage and human receptor). Details of EPA's exposure assessment methodology and modeling approaches are described in Section 6.3 of the Final Integrated Risk Assessment. In general, EPA's approach is expected to represent a high-end estimate of human and environmental exposure.

For each chemical, EPA evaluated exposure to worker via dermal and/or inhalation routes. Dermal exposures are estimated using the EPA/OPPT model for handling of liquids, and is intended to represent a conservative exposure scenario. The inhalation worker exposure estimates were based on personal breathing zone monitoring data from three literature studies that evaluated truck driver exposure to gasoline and/or total hydrocarbons during loading/unloading activities at fuel service stations after installation of vapor recovery system. EPA used the maximum exposure value from these studies to represent a conservative exposure scenario.

The cancer risk calculation assumes workers are exposed at the maximum 8-hr TWA concentration identified from the refinery monitoring data (as described previously), and that the same workers are continuously exposed at this level for 250 days per year over 40 working years in their lifetime. In other words, this assumes the workers handle the new chemical substance daily, perform activities with similar level of exposure to the new chemical substance, and work at the same refinery for their entire career.

EPA also evaluated exposure to the general population via the oral (from drinking water and fish ingestion) and inhalation (exposure to ambient air at the fenceline – 100 meters from facilities/activities) routes, and consumers via the dermal route.

5 Risk (methods and results)

EPA integrated available human health and environmental hazard data with relevant pathways of exposure to estimate risk to workers, the general population, consumers, and the environment. For each exposure pathway, EPA only reported risk for the lifecycle step that has the highest level of exposure to determine whether there is unreasonable risk to each human or environmental receptor through each pathway. The following section characterizes the risk assessment results; including some context around uncertainty. Additional risk estimates are presented in Section 7 of the Final Integrated Risk Assessment.

EPA used a margin of exposure (MOE) approach estimate non-cancer risk. MOE is calculated by dividing the POD value by the exposure concentration. Risk is identified for a given exposure

pathway if the calculated MOE is less than the benchmark MOE (which varies by POD), and vice versa.

EPA calculated cancer risk by multiplying the cancer slope factor by the chronic exposure concentration, assuming the human receptors are continuously exposed over their lifetime. EPA uses $1x10^{-4}$ (one in 10,000) as the benchmark for determining cancer risk to workers and $1x10^{-6}$ (one in a million) as benchmark for determining risk to consumers and the general population[13].

An overall summary of the risk landscape (some details provided below, full details in the risk assessment):

Number of 18 PMNs Where Risk Was Identified (By Endpoint and Lifecycle Stage)				
Human Health Receptor	Endpoint	Lifecycle Stage[1]		
		Manufacturing	Processing	Use
Worker	Non-Cancer	9	4	4
	Cancer	3	3	3
General Population	Non-Cancer	6	10	8
	Cancer	3	2	9
Consumer (Dermal Pathway only)	Non-Cancer	Not applicable Consumer exposures are relevant only for the use lifecycle stage		1
	Cancer			Not calculated (no appropriate hazard value)

[1]Includes all exposure routes (oral, dermal, inhalation). See narrative below for details. There are some cases with risk for more than one exposure route and more than one lifecycle stage.

5.1 Workers: Non-Cancer Risk Summary

For workers, non-cancer risks were identified via the inhalation pathway for 8 of the 18 PMNs. For seven of the 18 cases (P-21-0144, 146, 148 and 154-157), non-cancer inhalation risks were identified for workers at the refinery (manufacturing lifecycle stage of the new chemical substance). The risk estimates were based on exposure monitoring data for workers that perform various activities at the refinery. EPA used the maximum 8-hr time weighted average

[13] The Office of Air calculates "allowable "emissions for National Emissions Standards for Hazardous Air Pollutants (NESHAP). In their 2015 *Final Residual Risk Assessment for the Petroleum Refining Source Sector* (available at regulations.gov, EPA-HQ-OAR-2010-0682-0800), Appendix 9 provides the methodology and details for allowing emissons of maximum individual cancer risks of from 90 in 1 million to 100 in 1 million; or 9 in 100,000 and 1 in 10,000, respectively. d

(TWA) exposure value among the monitoring data and assumed all workers were potentially exposed at this concentration.

For four of the 18 cases (P-21-0144, 146 148, and 152), there were non-cancer inhalation risk estimated for workers from handling of the new chemical substance at the processing (bulk terminals) lifecycle stage. The highest exposures and risks were found during loading of liquid fuel products into tank trucks. For three of the 18 cases (P-21-0144, 148 and 154), there was also non-cancer inhalation risk estimated for workers at the end-use facilities (the last lifecycle stage).

For the worker inhalation exposure pathways, the hazard values were mostly from Tier 3 (individual constituents – some examples are dicyclopentadiene, 1-methyl naphthalene) POD values and they were adjusted to estimate the content of that constituent in the PMN substance. For example, if the constituent was believed to be approximately 6% of the PMN substance, the MOE calculation was adjusted accordingly.

Non-cancer risk to workers were also identified via the dermal pathway for five (P-21-0152-0156) of the cases; at the manufacturing/refinery lifecycle stage for all five and also for the processing (blending) and end-use lifecycle stages for one (P-21-0152) of the five casesThe hazard POD values for the dermal pathway were based on Tier 2 (analogous mixture) data.

5.2 Workers: Cancer Risk Summary

Cancer risks to workers via the inhalation pathway were identified for four (P-21-0147, 150, 152, 154) of the 18 cases. The highest cancer risk to worker was observed for P-21-0150 and was 3.1 in 1,000.

EPA believes this estimate and methodology represents a conservative, high-end estimate for the chronic exposure scenario.

Three of the four cancer estimates were at the manufacturing lifecycle stage and end use lifecycle stage (P-21-0147, 150, 154) and three were at one of the processing lifecycle stages (P-21-0147, 150, 152). For two (P-21-0147, 150) of the cases where cancer risk estimates exceeded 1 in 10,000 for workers for the manufacturing lifecycle stage, both also had excess cancer risk at a processing lifecycle stage and at the end use lifecycle stage.

As noted above, only four inhalation cancer hazard values (inhalation unit risk, or IURs) were identified – two with analogous mixtures and two with constituents. In two of the four cases Stoddard solvent (Tier 2, analogous mixture) was used and for the other two benzo(a)pyrene (Tier 3, constituent) was used with a relative potency factor adjustment to estimate potency of PAHs with four rings instead of five. For the cases with benzo(a)pyrene, it was assumed that approximately half (for one case) or, less than 5% (for the second case) of the PMN substance was assumed to contain that constituent. The highest cancer risk estimate case used Stoddard solvent mixture, and the PMN substance was assumed to be 100% Stoddard solvent. Adjusting

the amount of analogue/constituent in the PMN substance affects the risk estimate. For the constituent adjustments, the risk estimate is reasonable given the knowledge of the chemical composition. However, use of 100% Stoddard Solvent to represent the PMN substance is expected to be an overestimation of the risk.

5.3 General Population: Non-Cancer and Cancer Risk Summary from Drinking Water and Fish Ingestion

For 10 of the cases (P-21-0144, 145, 148-150, 152, 155-158), non-cancer risks above 1 in a million were estimated for the general population for systemic and/or oral portal-of-entry effects via either drinking water (adult or infant) or fish ingestion. None of the 10 cases were associated with the manufacturing lifecycle stage, six were associated with risk from the processing lifecycle stage and four were associated with the end use lifecycle stage. The hazard POD values came from both analogous mixtures and individual constituents. Again, the fraction of the PMN substance containing the constituent was adjusted based on the available information.

EPA predicted levels of the new chemical substance in surface water at the point of release and did not incorporate downstream environmental fate and transport of the chemical. Where site-specific flow data were not available, EPA modeled the concentration using water stream flows of a representative industry sector in the E-FAST database, which generally resulted in a more conservative estimate of water stream concentration. EPA used the 30Q5 water stream flow to estimate acute drinking water and fish ingestion exposures. EPA used the highest bioconcentration and bioaccumulation factors to calculate fish ingestion exposures. These assumptions result in conservative, high-end exposure estimates.

Cancer risk estimates above 1 in million were also identified for the general population via the oral route (either from drinking water, fish ingestion, or both) for five cases (P-21-0152, 155-158). As presented in Section 7.2.2 of the Integrated Risk Assessment, P-21-0152 showed the highest cancer risk estimates for drinking water and fish ingestion, both exceeding the one in a million benchmark for the general population. These estimates are based on potential water releases from cleaning of tank truck and bulk fuel storage tank from a single unknown fuel blending facility (the processing and end use lifecycle stages). For the oral cancer hazard slope factor, all three cases used a single constituent (either benzo(a)pyrene with a relative potency factor adjustment to estimate potency of PAHs with four rings instead of five or 1-methylnaphthalene). The highest cancer risk estimate used benzo(a)pyrene with the constituent content in the PMN substance adjusted accordingly.

EPA used the following conservative assumptions when estimating cancer risk for this pathway:

- EPA made conservative assumptions on the environmental release media and release frequency. While the Effluent Limitation Guidelines and Pretreatment Standards at 40 CFR Part 442, Subpart A requires an effective heel management program for

transportation equipment, there is some potential for cleaning residuals to be sent to a wastewater treatment plant in addition to other means of waste disposal (e.g., incineration or landfill). In addition, EPA assumed that bulk fuel storage tanks would be inspected and cleaned once per year with the cleaning residuals potentially released to wastewater treatment, incineration or landfill. EPA assumed both releases occur at the same location. In practice, tank trucks are typically cleaned by a third party, and that bulk storage tanks are typically cleaned at a lesser frequency (note API standard requires internal inspection of petroleum storage tanks once every 10 years). EPA did not assume direct discharge of these sources as existing SPCC regulations would also prevent direct discharge of petroleum products to surface water.

- EPA determined the bioaccumulation potential for the new chemical substance by evaluating all constituents within the PMN substance (a mixture) and identifying the constituent with the highest BCF/BAF value. For the case with the highest cancer risk for the general population via the oral mentioned earlier in this section (P-21-0152), EPA used 1-phenyl-5-hexylnapththalene to inform the bioaccumulation potential; this constituent is part of the three ring aromatics group of chemicals that make up on average [redacted] of the total PMN mixture.
- EPA modeled chronic drinking water and fish ingestion exposure using a conservative default exposure duration value of 33 years, which represents the number of years a person may drink contaminated water or eat contaminated fish, respectively.

5.4 General Population: Non-Cancer and Cancer Risk Summary from Inhalation Exposure

For eight (P-21-0148, 149, 152, 154-158) of the 18 cases, non-cancer risks were identified for the general population for systemic and/or inhalation portal-of-entry effects via either fugitive air or stack air inhalation. Depending on the case, these risks were associated with various lifecycle stages of the PMN substance. Seven included end use lifecycle stages, five included processing, and six also included the manufacturing lifecycle stage. Where there are multiple release sources from a given lifecycle stage, as a screening-level approach, EPA modeled all releases as coming from a single stack, all fugitive air releases as coming from a single release source, and assumed that human exposure occurs at the fenceline (100 meters away from the source). EPA expects these assumptions would result in conservative risk estimates.

The estimates (listed in the "stack" column in Section 7.2.2 of the Integrated Risk Assessment) represent inhalation risks associated with combustion of fuels during end-use which were modeled using a stack emission scenario as an approximation because EPA does not have an appropriate exposure scenario/model to estimate this use. The modeled scenario does not represent a realistic exposure scenario and there is a high level of uncertainty associated with these estimates due to the methodology and assumptions used in the assessment:

- EPA assumed more than [redacted] (all) of the new chemical substance (for P-21-0152 and [redacted] for P-21-0158) in fuel products are distributed to and used at 100 sites, an estimate provided in the submission. These "use sites" likely represent fuel distribution/dispensing facilities (e.g., gasoline stations, airports) rather than the actual end-use location (e.g., gasoline and jet engines), which are mobile sources. However, the modeled scenario assumes all fuels would be burned at these sites.
- EPA modeled the air concentration of the PMN substance at the fenceline (100 meters away) using the same modeling parameters as stack incineration. The modeling assumption for stack incineration is based on combustion of the PMN substance in a municipal incinerator operating at temperatures below 1800 degrees F. This approach does not reflect actual fuel combustion in engines, which occurs at a higher temperature and does not reflect the mobile nature of the end use combustion.
- The modeling also uses Destruction and Removal Efficiency (DRE) associated with stack incineration. The DRE range was 0% to 99.9% for constituents of P-21-0152 and 0158; however, the DRE used in the assessments was 0% based on the presence of polycyclic aromatic compounds. The modeling does not further adjust the DRE value based on actual polycyclic aromatics content. For P-21-0158, the polycyclic aromatics content is 9 percent in the PMN substance. These DRE values may not accurately reflect breakdown of these compounds in gasoline and diesel engines, and the presence of emission controls such as catalytic converter installed on cars.
- The modeling approach assumes a "stationary" emission source and does not reflect the true nature of a mobile source emission scenario. As an example for P-21-0158, the modeled scenario effectively assumes that [redacted] of the new chemical substance are burned at [redacted] locations (likely airports), that every plane at the airport was idling at the same time on a runway burning an entire tank's fuel without ever taking off, that components of the fuel that contribute to cancer risk are not fully combusted and are present in the exhaust, and that residents living nearby would continuously breathe the exhaust each day at a distance of 100 meters over many years in their lifetime.
- The modeled exposure estimates for these cases exceeded the PODs used for estimation of the IURs, so the IURs could not be used to accurately estimate cancer risk.

For five of the eight cases, Tier 3 constituent hazard POD values were used (two were used: benzo(a)pyrene [for two cases; ranges of constituent content in the PMN substance was between [redacted] and 1-methylnaphthalene [for three cases, range in constituent content was between [redacted] For the other three cases analogous mixture PODs were used.

Cancer risk estimates above 1 in a million were identified among six (P-21-0147, 148, 150, 152, 154, 158) of the 18 cases. The highest cancer risks identified were from P-21-0152 and P-21-0158, and were as high as an extra cancer risk 1 in 4. For the hazard inhalation unit risk values, three used an analogous mixture (Stoddard solvent, PMN substance assumed to be 100%

Stoddard solvent), and the other three used either benzene (one PMN case, less than 1% constituent content in the PMN substance) or benzo(a)pyrene (constituent content – either less than 5% or about half). Due to the limitations noted above, the modeled scenario is not an exposure scenario that would ever actually occur and the calculated cancer risks are expected to significantly overestimate actual exposures and risks.

5.5 Consumer Risk Summary

Risks to consumers were identified for the dermal pathway for P-21-0155. The hazard POD value was based on an analogous mixture (Tier 2). EPA modeled exposure to consumers using the P_DER2a model within CEM. This model estimates dermal exposure based on the absorbed dose of a chemical from a thin film applied onto the skin. EPA used high-end estimates for exposure duration and mass of product used in the acute scenario. For the chronic scenario, EPA assumed the same consumers would be continuously exposed to the PMN substance for 57 years.

5.6 Risk to the Environment

EPA integrated available environmental hazard data with relevant pathways of environmental exposure to estimate risk to ecological receptors. Risks to the environment were evaluated by comparing estimated surface water concentrations (SWCs) with the acute and chronic concentrations of concern (COCs). When evaluating risks from chronic exposures, the number of the days of exceedance (SWC > chronic COC) is also considered in the risk assessment.

Acute environmental risk was identified for 12 of the 18 cases (See Section 7.1 of the Integrated Risk Assessment). These risks are associated with potential water releases from the processing and end use lifecycle stages downstream from the Chevron refinery. EPA conservatively assessed some potential releases to water from cleaning of tank trucks and bulk tanks used to transport or store the fuel products containing the PMN substances, and modeled the resulting surface water concentration using the 7Q10 flow rate (i.e., the lowest 7-day average flow that occurs [on average] once every 10 years). EPA predicted these surface water concentrations at the point of release and did not incorporate downstream environmental fate and transport of the chemical.

Chronic environmental risk was not identified for any of the 18 cases due to the expected low frequency (days per year) of potential water release.

6 Summary

In 2022, EPA performed a TSCA new chemical risk assessment on 18 separate premanufacture notices (PMNs) for chemical substances intended to be used as alternative fuel sources. This

document provides additional information to further describe the risk assessment approach and risk estimates presented in EPA's 2022 integrated risk assessment[14].

Each of these 18 PMN substances is a complex mixture comprised of different ratios of paraffinic, isoparaffinic, naphthenic, olefinic, and aromatic (PIONA) molecules. The new chemical submissions provided the EPA with measured PIONA profile information for each new chemical substance. There were no toxicity (hazard) information submitted with the new chemical submissions. The measured PIONA profiles do not show significant variation from that of a traditional petroleum fuel stream. EPA used the PIONA profile in its human health and environmental hazard assessment using a tiered approach for identifying the appropriate hazard value(s) for use in the risk assessment. This tiered approach is a screening-level method and uses assumptions that are conservative (i.e., health protective).

In evaluating exposure, EPA determined that the 18 PMN substances are expected to follow the typical lifecycle of petroleum-based fuels. EPA uses a suite of models[15] and conservative assumptions to estimate environmental release and exposure to ensure the assessment is protective of human health and the environment.

When coupled together, the conservative assumptions for both the hazard and exposure assessments for the 2022 integrated risk assessment for the 18 PMN substances led to an overestimate of risk. For example, as described in Section 5.4 of the 2022 integrated risk assessment, the assessment resulted in an estimated extra cancer risk of 1 in 4 for people exposed 100 meters ("fenceline") from the end-use (combustion) of one of the PMN substances (a jet fuel). However, this exposure scenario, as described in Section 5.4 in this document, is not one that would realistically ever be expected to occur.

Given the short time-frame for new chemical reviews and the similarities in the PIONA profiles to traditional fuels, instead of using additional resources to develop a refined and more accurate estimate of the human health risks posed by these 18 PMN substances, EPA determined that the similarities in the PIONA profiles supported the assumption that worker and fenceline community risk from these PMN substances are similar to those of existing petroleum fuels and applied appropriate risk mitigation measures to protect both human health and the environment. Specifically, EPA's consent order required the company to comply with existing regulations under the Clean Air Act, OSHA, DOT, and Coast Guards as well as anything else that was applicable to the manufacture, transportation, storage, dispensing, use and disposal of these new fuels (see Docket # EPA-HQ-OPPT-2023-0245 in regulations.gov for copies of the final consent order for these 18 PMNs).

[14] U.S. EPA. 2022. *Integrated Risk Assessment for Chevron Waste Plastic Fuels (P-21-0144, 145, 146, 147, 148, 149, 150, 152, 153, 154, 155, 156, 157, 158, 160, 161, 162, and 163)*

[15] https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca